General Import Authorisation Number	IMP/GEN/2024/09

Department for Environment Food & Rural Affairs

Commission Regulation (EU) 142/2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive **("Regulation 142/2011")**
The Trade in Animals and Related Products Regulations 2011
Animal By-products (Enforcement) (England) Regulations 2013

GENERAL IMPORT AUTHORISATION

The Secretary of State for Environment, Food and Rural Affairs, by this authorisation issued under Article 27 of Regulation (EU) 142/2011 authorises to land in England, subject to and in accordance with the conditions set out below:

Treated milk and milk-based products and treated blood products **(not exceeding 3% concentration)**, for use as a stabiliser or carrier for any of the following materials:

- Monoclonal and polyclonal antibodies, proteins, enzymes, peptides and polypeptides separated from plasma or serum and purified to the extent that they do not contain any viable pathogenic microorganisms
- Cells which do not contain a pathogen
- Cell cultures more than one generation removed from tissue harvested from an animal
- Stem cells derived from animals born and reared exclusively in a laboratory environment
- Material other than animal by-products or derived products

FOR RESEARCH AND DIAGNOSTIC PURPOSES ONLY (NOT FOR RESALE)

From

Must come from a country listed for the relevant category of product in the column headed "Third countries' lists" in—

a. for treated milk and milk-based products, Table 1 in Section 1 of Chapter 1 of Annex 14 to Regulation 142/2011; and
b. for treated blood products, Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011.

At

Any point of entry in England

[Until further notice or unless revoked by the Secretary of State]

Signed on behalf of the Secretary of State for the Environment, Food and Rural Affairs:

Name: C. Parsons Date:

Department for Environment, Food and Rural Affairs
29 MAY 2024

Conditions attached to this authorisation

Packaging

1. The material must be packed in leak-proof sealed containers.

2. All inner and outer packaging must be swabbed with suitable disinfectant before leaving the exporting address.

3. The packaging must be clearly labelled to indicate the nature of the product, that this is intended for *in vitro* use for research and that it is **not** for human or animal consumption.

4. Irrespective of the mode of transport, all specimens must be packaged so that they fully comply with the requirements of relevant Post Office or International Air Transport Association (IATA) regulations.

5. The products must remain in their original wrapping at all times until their arrival at the destination address on page 1.

Import Documentation

6. Each consignment must be accompanied by a copy of this import authorisation and a commercial document signed by a senior manager of the facility, on company letter headed paper dated no less than 2 months from the date of import of each consignment which must confirm:
    i. The description of the material and the animal species of origin;
    ii. The category, 1, 2 or 3, of the material as defined in Articles 8, 9 or 10 of Assimilated Regulation (EC) No 1069/2009;
    iii. The quantity of the material;
    v. The name and address of the establishment or plant of origin of the material and its approval or registration number assigned in accordance with Regulation (EC) No 1069/2009 or, where applicable, in accordance with Regulations (EC) No 852/2004, (EC) No 853/2004 or (EC) No 183/2005 of the European Parliament and of the Council;
    vi. The name and the address of the consignor;
    vi. The name and address of the establishment or plant of destination and the registration or approval number assigned in accordance with Regulation (EC) No 1069/2009 or, where applicable, in accordance with Regulations (EC) No 852/2004 or (EC) No183/2005;
    vii. That the product complies with the conditions set out in this general import authorisation with reference number **IMP/GEN/2024/09.**

Transportation

7. The consignment must be sent directly from the point of entry into Great Britain to the authorised user at the destination address on the commercial document.

8. The material must be transported, handled and labelled in accordance with the Animal By-products Regulations.

9. The transporter and destination address must be registered or approved (see note G) in accordance with the relevant Animal By-Products (Enforcement) Regulations, (ABPE) before commencing operations.

Storage, Use and Handling

10. None of the material to which this authorisation relates shall be used for human or animal consumption under any circumstances.

11. The samples and material derived from the samples shall be for in vitro use only.

12. Any subsequent use of these products for purposes other than those referred to in point 38 of annex 1 of Regulation (EU) No 142/2011, is prohibited.

13. Users shall take all necessary measures to avoid the spreading of diseases communicable to humans or animals during the handling of the materials under their control, in particular by way of the application of good laboratory practice.

14. Samples must be handled and stored under containment level conditions which are appropriate to the risks presented by the product. This should be determined by the operator, following a suitable risk assessment, in accordance with The Control of Substances Hazardous to Health Regulations 2002.

15. Unless they are kept for reference purposes or re-dispatched to the third country of origin, research and diagnostic material, products derived from their use and waste shall be disposed of appropriately, in accordance with The Waste (England and Wales) Regulations 2011/The Waste (Scotland) Regulations 2012 or Section 1 of Chapter III of Annex XIV Regulation (EU) 142/2011.

16. Importers shall keep a register of consignments of samples imported under this authorisation, which should contain the information referred to in condition 6 above as well as the date and method of disposal.

Other Import Conditions

17. The product meets the requirements specified—
    a) for treated milk and milk-based products, in entry 4 of Table 1 in Section 1 of Chapter 1 of Annex 14 to Regulation 142/2011; or
    b) for treated blood products—
        i. in entry 2 of Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011; or,
        ii. in entry 3 of Table 2 in Section 1 of Chapter 2 of Annex 14 to Regulation 142/2011 and have been treated in accordance with the requirements in point 2(b)(ii) of Chapter 4 of Annex 13 to Regulation 142/2011.

18. The animal by-product used as the stabiliser or carrier is at a concentration of 3% or less of the entire product, with no limit on the individual unit size.

19. Any breach of these conditions must be reported to the APHA Imports Team, Centre for International Trade, Carlisle.

NOTES

A. References to European Union (EU) legislation within this document are references to direct EU Legislation which has been assimilated in Great Britain (assimilated direct legislation), as defined in the Retained EU Law (Revocation and Reform) Act 2023 and can be viewed on the UK legislation website (legislation.gov.uk).

Further information regarding changes to the import controls from an EU country from 31 January 2024 can be found on GOV.UK at:

https://www.gov.uk/government/publications/risk-categories-for-animal-and-animal-product-imports-to-great-britain

B. **A copy of this authorisation is required to accompany the consignment.**

C. Please note that while this authorisation was current at the time of its issue, conditions can be subject to frequent change and importers are advised to check they are using the current version on gov.uk General licences and authorisations to import live animals or animal products - GOV.UK (www.gov.uk)

D. It is the responsibility of the importer to follow good laboratory practice standards and to prevent the sample entering the environment in any manner.

E. In accordance with Annex VIII, Chapter III, point 5 of Regulation (EU) No 142/2011, all records and related documentation associated with material imported under this authorisation must be kept for a minimum of 24 months for presentation to the competent authority.

F. Any products and records, relating to the product imported under this authorisation, shall be made available if so required for inspection by an Officer of the Animal and Plant Health Agency at any place nominated by them for such inspection. The importer or their agent shall afford all assistance necessary to such an officer to enable the inspection in such a manner as the Officer shall determine. The importer shall be responsible for meeting any costs of carrying out such an inspection.

G. For information on registration/approval, please see the website: https://www.gov.uk/animal-by-product-categories-site-approval-hygiene-and-disposal#getting-your-site-approved-or-registered

H. This authorisation is granted under animal health import legislation and gives no exemption from any prohibition, regulation or restriction imposed by any other Government Department or Agency.

CAUTION

It is the importer's responsibility to ensure that any import covered by this authorisation complies with the terms and conditions as set out. If you cannot comply with any of the conditions above, please contact the APHA Imports Team, Centre for International Trade, Carlisle.

Any breach of any conditions attached to this Authorisation will constitute an offence against regulation 39 of the Trade in Animals and Related Products Regulations 2011 (as amended) or regulation 17 of the Animal By-products (Enforcement) (England) Regulations 2013.

CONTACT FOR FURTHER INFORMATION

Animal and Plant Health Agency, Imports Team
Centre for International Trade – Carlisle

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